density, and myocyte width was measured with 400x on 1 μm slides by light microscopy. Interstitial tissue was expressed as % of total area.

Results: The stenosis reduced mean LAD flow from 0.90 ± 0.12 to 0.55 ± 0.12 ml/min/g and wall thickening from 38 ± 3% to 10 ± 6%. After 4 weeks of reperfusion, wall thickening in HM recovered to 28 ± 4%. Results of the microscopic study are presented in the table:

	Control	Day 7 of Stenosis	Reperfusion
Myocyte Density	57 ± 1	45 ± 4*	54 ± 3
Myocyte width (um)	17.7 ± 0.3	22.2 ± 2.0*	18.7 ± 0.9
Interstitial content (%)	12.0 ± 0.2	17.8 ± 2.3*	16.1 ± 1.4*

*p < 0.01 compared to baseline

Conclusions: Reperfusion of hibernating myocardium for 4 weeks restores myocyte number across the LV wall, indicating recovery in the arrangement of myocyte bundles and partial regression of myocyte hypertrophy.

1004-135 Increased Cytokine Levels and Thrombin Generation in Stable Angina are Reduced by Aspirin. A Randomised, Controlled, Cross-over Trial

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Backround: Recently, the reduction of the risk for myocardial infarction by aspirin (ASA) has been attributed to its antiinflammatory properties even when administered at low doses. Macrophage colony stimulating factor (MCSF) causes macrophage/monocyte activation and thus, release of vasoactive substances, interleukins 1b (IL1b) and 6 (IL6) and tissue factor. Our aim was to investigate whether high cytokine levels and increased thrombin generation a) occur in stable angina (SA) b) are related to transient myocardial ischaemia and c) are reduced by aspirin

Methods: We measured prothrombin fragments (PF1 + 2, nmole/l) MCSF, IL1b, IL6 (pg/ml) plasma levels in 60 patients with SA and in 21 healthy contols by ELISA. Samples were obtained at the end of a 48 h Holter monitoring (HM). All patients had angiographically documented disease and positive exercise test. Fourty patients had ischaemia in HM and were randomly treated with ASA 300 mg, o.d. or placebo for 3 weeks in a double blind, cross-over trial.

Methods: PF1 + 2, MCSF, and IL6 were increased in patients with SA compared to controls (table, p < 0.01). Analysis of variance showed that MCSF and IL1b increased according to the number of diseased (1-2-3) vessels (p < 0.05). Only MCSF was higher in patients with ischaemia in HM than those without (1124 + 651 vs 528 + 417, p < 0.01). Although, PF1 + 2 and cytokine levels were decreased by ASA (table, p < 0.05), they remained higher than those in controls (p < 0.05)

	SA	ASA	CONTROLS	p
PF1 + 2	2.26 ± 1.8	1.73 ± 1.2	0.93 ± 0.5	<0.01
MCSF	1076 ± 613	950 ± 567	479 ± 287	<0.05
IL6	4.2 ± 1.3	3.5 ± 0.8	2.0 ± 0.9	<0.05

Conclusion: Elevated cytokine and PF1 + 2 plasma levels in SA suggest the presence of enhanced inflammatory activity and increased thrombin generation. Only MCSF was related to both extent of disease and daily life ischaemia. Reduction of the above factors by ASA may represent an additional mechanism of its therapeutic action in coronary artery disease.

1004-136 Estrogen and Progesterone Decrease Lipid Loading in Human Female Macrophages

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Background: Based on the lower incidence of atherosclerosis in females, we hypothesized that estrogen and progesterone may reduce lipid-loading in human macrophages (ie. foam cell formation).

Methods: Monocytes from healthy female donors (n = 5) were plated out in phenol-red free RPMI and allowed to differentiate into macrophages over 10 days. Cells were treated from days 2–10 with either control media, 17-estradiol (2 nM and 200 nM) ± the estrogen receptor antagonist ICI 182 780, diethylstilbestrol (DES, non-steroidal estrogen), 17α-estradiol (17α-E, inactive stereoisomer) or progesterone 10 nM. Lipid-loading was assessed by HPLC after a 48 hr incubation (days 8–10) with acetylated LDL in lipoprotein-deficient human serum. Triplicate wells were used for each condition, in each experiment.

Results: Macrophages treated with 17β-estradiol showed a significant dose-related reduction in cholesterol ester formation vs controls (88 ± 12% and 78 ± 14% for 2nM and 200nM estradiol respectively vs 100 ± 5%, p = 0.04 by ANOVA). There was a similar trend in the levels of free and total cholesterol (p = 0.06). These effects were not blocked by ICI 182 780. Progesterone alone (10 nM) was also associated with a marked reduction in cholesterol ester loading (16 ± 5%, p < 0.001). In contrast, DES and 17α-E did not reduce lipid loading. Estrogen exposure in male macrophages (n = 4), showed no significant effect (99 ± 13%).

Conclusion: 17β-estradiol and progesterone reduce lipid loading in human female macrophages, consistent with an atheroprotective effect.

1005 Coronary Stenting: Procedural Considerations

Sunday, March 29, 1998, 5:00 p.m.–7:00 p.m.
Georgia World Congress Center, West Exhibit Hall Level
Presentation Hour: 5:00 p.m.–7:00 p.m.

1005-77 Improved Procedural Results of Coronary Stenting With Focal Balloon "Overexpansion" – Final Core Lab Analysis From the Prospective, Multicenter OSTI-2A Trial

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The primary determinant of late outcome following coronary stenting is the min. stent dia. (MSD) or min. stent area (MSA) achieved. Stent expansion continues to increase as pressure is raised from 12 to 18 atm. To study whether luminal dimensions can be safely further increased by using *oversized balloons* at high pressure, Palmaz-Schatz stents were implanted at 18 atm. in 143 consecutive lsns in 120 pts at 7 centers. IVUS was performed, and if ≥0.7 mm of vessel remodeling was present at the lesion (external elastic membrane dia. - ref. segment lumen dia. ≥0.7 mm), the stent was further expanded with a balloon ≥0.5 mm larger at 16 atm. To minimize edge dissections found in prior trials of aggressive stenting, a novel focally expanding balloon was used which grows 0.5 mm larger centrally (within the stent) than outside the stent (the CVD FACT™). QCA and IVUS were performed pre, post standard stenting, and post focal stenting, and analyzed at independent core labs (Stanford).

Results: By QCA, the baseline mean ref. dia. was 3.02 ± 0.48 mm and MLD was 1.10 ± 0.53 mm. Remodeling was present to permit focal stent "overexpansion" in 120 of 143 lsns (84%).

	standard stenting	focal stenting	p value
Mean balloon dia	3.36 ± 0.37	3.87 ± 0.37	< 0.0001
Balloon-artery ratio	1.12 ± 0.17	1.33 ± 0.20	< 0.0001
MSD (mm) - QCA	2.78 ± 0.43	2.93 ± 0.44	< 0.0001
MSD (mm) - IVUS	2.77 ± 0.39	2.95 ± 0.38	< 0.0001
MSA (mm^2) - IVUS	7.29 ± 1.89	8.22 ± 1.90	< 0.0001

By QCA, dissections were present at 4 stent edges after standard balloons and 1 stent edge after focal upsizing. No perforations, subacute thromboses or major ischemic complications occurred.

Conclusions: Balloons traditionally considered oversized, applied focally within the stent borders, may safely be used in the majority of lesions, and result in improved luminal dimensions.

1005-78 Is High Pressure Inflation Necessary for Optimal Stenting?

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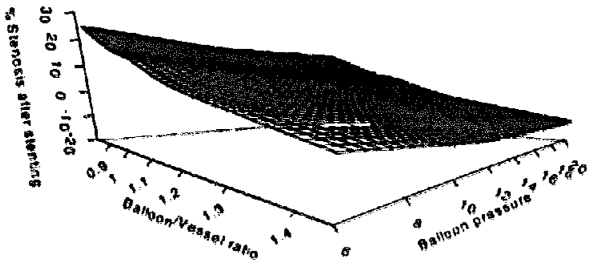
High pressure inflation after coronary stent placement has been employed to achieve optimal stent deployment. However, it is not clear whether this is due to more radial force generated by high pressure inflation or simply by bigger balloon size. Quantitative angiographic analysis we performed on 2724 lesions (2096 patients). The adequacy of stent deployment was based on percent diameter stenosis (DS) immediately after stent placement. Balloon to vessel ratio (BRD) and balloon pressure (BP) correlated with DS, but there was a much stronger correlation for BRD (r = −0.63 vs. r = −0.21, p < 0.001). When both BRD and BP were entered in a multivariate stepwise linear regression analysis (DS as a outcome variable), together with other factors, a significant independent role could be documented only for BRD (β = −0.641, p < 0.001).



Conclusion: High balloon pressure may not be important as long as an adequate balloon to vessel ratio is maintained. This data indicates also that balloon to vessel ratio is crucial for adequate stent deployment.

1005-79 High Versus Normal Balloon Pressure Dilatation for Coronary Stent Placement. 6-Month Clinical and Angiographic Results From a Randomized Multicenter Trial

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Background: The impact of high balloon pressure for stent placement on clinical and angiographic outcome is still under discussion.

Methods: From May 96–May 97, 1126 patients were randomized to either "high pressure" implantation (575 interventions in 853 lesions; balloon pressure 16.7 ± 2.3 atm) or "normal pressure" implantation (572 interventions in 843 lesions; balloon pressure 11.1 ± 2.3 atm). Per protocol, only patients with cardiogenic shock or mechanical ventilation prior to the intervention, patients which already had been stented in the same vessel and patients without consent were excluded.

Results: Complete 4-week follow-up data are currently available in 98.4%. No significant differences in major adverse cardiac events (MACE) or the rate of stent thrombosis were seen between the two treatment groups (overall MACE rate 3.8%). As of today, 750 patients were eligible for 6-month follow-up (i.e. patients with successful stenting before January 31, 1997 and without MACE at 4 weeks) which has been completed in 85% of eligible patients.

Conclusions: These preliminary data suggest that early results are not significantly different. A complete clinical and angiographic 6-month follow-up will be available.

1005-80 Does Systematic High Pressure Deployment Improve Clinical Outcome After Palmaz-Schatz Coronary Stent Implantation?

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Previous reports emphasized the intravascular echography benefit of systematic high pressure (HP) stent deployment but its clinical benefit is still questionable. Since 01/94, we systematically used HP then, from 05/95 to 12/96, we decided to change our policy using an 8 to 12 atm. pressure and only more pressure in case of residual balloon indentation or stenosis ≥10%. We compared all consecutive Palmaz-Schatz stent implantations during these two time periods. Both groups received a ticlopidine/aspirin drug regimen. In HP group (N = 337 pts, 88% of stents with pressure ≥15 atm.) and regular pressure group (RP, N = 305 pts, 88% of stents with a pressure < 15 atm.), clinical data were similar but a higher rate of acute MI PTCA in RP group. Angiographic data analysis revealed a higher rate of LAD PTCA and B2/C type lesion in RP pts. Procedural data and stent indication were similar in both groups, except pressure. In-hospital (InH) and 1 year follow-up (Fup) clinical results were (MACE = Death, Q MI, CABG):

	HP	RP	p
Clinical success (%)	97	98	NS
Stent thrombosis (%)	1.2	1.3	NS
InH MACE (%)	3	2	NS
Fup TLR (%)	13	10.6	NS
Fup MACE (%)	8	4.3	0.07
Event-free survival rate (%):	77.4	83.8	0.05

Thus, in our experience, a systematic use of HP Palmaz-Schatz stent deployment is not beneficial.

1005-81 Cost Impact of High Pressure Inflations and Therapy With Aspirin and Ticlopidine After Coronary Stenting

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Post-stent high pressure inflations (HPI) with aspirin and ticlopidine (AT) decrease subacute thrombosis and vascular complications (VC). To determine their influence on procedural and hospital costs, PTCA with stent placement for non-bailout indications (elective, suboptimal result post-balloon) in 663 patients (719 lesions) were reviewed; the initial 335 patients received coumadin (C) and no-HPI and the recent 328 patients received HPI and AT. Although the cost of devices currently used for non-bailout stent placement is slightly higher, total hospital costs have been reduced with HPI and AT, due to shorter hospital stay, less in-hospital CABG and less VC (table).

	No HPI + C	HPI + AT	P Value
Elective (%)	183 (55)	193 (59)	ns
Suboptimal Result (%)	152 (45)	135 (41)	ns
# Stents/Pt	1.2 ± 0.5	1.4 ± 0.7	< 0.0001
IVUS (%)	28 (8.4)	67 (19.5)	< 0.0001
In-Hospital CABG (%)	13 (3.9)	2 (0.6)	0.005
Vascular Complications	61 (18.3)	15 (4.6)	< 0.0001
Death	6 (1.8)	2 (0.6)	0.29
Length of Stay (days)	6.5 ± 4.7	2.4 ± 5.1	< 0.0001
Device Cost ($)	2729 ± 1003	3391 ± 1375	< 0.0001
Total Hospital Cost ($)	12,488 ± 6404	8752 ± 3795	< 0.0001

High pressure inflation with aspirin and ticlopidine have clearly improved patient care; outcome has improved dramatically while hospital costs have fallen.

1005-82 Assessment of Optimal Stent Implantation Using Computerized Pressure-Volume Curves

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Optimal stent deployment (D) is crucial to ensure short- and long-term patency and may require additional IVUS, an invasive and expensive tool. Pressure volume curves (PVC) of balloon inflation derived from our Computerized Automatic Pressure Sensor and Implantation Device (CAPSID), reflect resistance to stent opening. We calculated the area index between the PVC inside the stent (restrained inflation) and the PVC in air (unrestrained inflation). This area index that reflects the restrain imposed by the stent to balloon inflation, correlated with IVUS-MUSIC criteria for stent D: optimal D (group 1, 5 patients), borderline D (group 2, 6 patients) and poor D (group 3, 4 patients):

IVUS	Group 1	Group 2	Group 3
PVC area**	7.6 ± 4.5*	33.3 ± 12.1*	80.5 ± 48.3*

* p < 0.05 between all groups, ** normalized index × 1000

In 10 patients in whom angiography suggested need for higher pressure inflations, the area index decreased from 72.3 ± 3.4 to 26.9 ± 9.1. Ten patients who did not require additional inflation had an average area index of 19.9 ± 8.5 and a good outcome.

We Conclude: CAPSID PVC are a good guide for stent D and the need for further inflation, with good correlation to IVUS assessment.

1005-83 Transradial Approach for ad hoc Coronary Interventions: Procedural Results and Vascular Complications

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Background: Percutaneous transradial approach (PTRA) has the potential for low vascular complications, immediate post-procedural sheath removal and early ambulation. This series evaluate the safety and efficacy of this technique for the first 3053 consecutive procedures (proc.) during learning curves of 6 interventional cardiologists.

Results: Between July 94 and June 97, PTRA was attempted in 3053 proc in 2597 patients (pts), 73% male, with a functional radial arterial arch. In 260 pts, PTRA was performed up to 5 times, days to months later. Mean age was 60 years (17–94) with a wide range of weight (33–152 kg) and height (1.1–2.0 m). Coronary angiography was performed in 1560 pts (same-day discharge in 58%), *ad hoc* (78%) or elective angioplasty was performed in 1493 pts including coronary stenting in 670 pts. PTRA was not possible in 295 proc. (9.6%). Unsuccessful radial artery canulation (208), anatomical variation (49),